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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,389	DILLON ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8,11 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8,11 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1, 3, 4, 8 and 15) and SEQ ID NO: 52 in the reply filed on September 18, 2006 is acknowledged. The traversal is on the ground(s) that sequences with SEQ ID NOs 74, 83 and 154 should be examined together with SEQ ID NO: 52, since these sequences correspond to different regions of the same tumor antigen, therefore search for one of these sequences would lead to art related to the other. This is not found persuasive because the claims are not drawn exclusively to nucleic acids comprising SEQ ID NO: 52, or 74, or 83, or 154, but also to their fragments or sequences hybridizing to them under moderately stringent conditions. Therefore, search for a 20 bp fragment of SEQ ID NO: 52 would definitely not lead to a reference disclosing a 20 bp fragment of SEQ ID NO: 74, for example. Further, a sequence which hybridizes to SEQ ID NO: 52 would most certainly not hybridize to any other of the sequences. Applicants further traverse an objection to claims 9-13 and 17 as being of improper multiple dependent format, arguing that these claims are Markush claims therefore the format is proper. However, these claims are not Markush claims in the sense that all of the claimed compounds are totally unrelated to each other in terms of structure and function.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Claims 1, 3, 4, 8, 11 and 15 will be considered with respect to SEQ ID NO: 52.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on September 6, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

5. The disclosure is objected to because of the following informalities: the first paragraph does not contain updated information regarding the status of parent applications.

Appropriate correction is required.

Priority

6. The instant claims are given a priority date of March 10, 2000, the filing date of parent application No. 09/523,586, where SEQ ID NO: 52 was first disclosed.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1, 3, 4, 8, 11 and 15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's

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assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a real world use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

Polynucleotide with SEQ ID NO: 52 is the cDNA sequence of contig 11 (page 9, line 20). In Example 1 (pages 98-102), Applicants explain that sequence was obtained from metastatic breast tumor library. No further information about the sequence or a protein encoded by it was provided, therefore, the function of the protein is unknown.

The claimed polynucleotide (SEQ ID NO: 52) is not supported by a specific asserted utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to a wide variety of polynucleotides. The specification states that the polynucleotides may be useful as hybridization probes, PCR primers (page 32, lines 14-37; page 38, lines 14-29; page 39; page 40, lines 1-23), for encoding of polypeptides (page 52, lines 26-29; page 53-56), for sequence comparisons with other polynucleotides (page 33, lines 17-25), for mutagenesis to provide derivative polypeptides (page 35, lines 28, 29; page 36, 37), as antisense oligonucleotides (page 40, lines 24-29; page 41; page 42, lines 1-12), for design of ribozymes (page 42, lines 13-29; page 43, 44; page 45, lines 1-25), parts of expression vectors and for gene therapy and vaccines (page 71,

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lines 10-29; page 72-74). These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed.

Further, the claimed polynucleotide compound is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compound such that another non-asserted utility would be well established for the compounds.

Applicants state in lines 23 and 24 of page 15 that the compositions described in the specification could be used for the therapy and diagnosis of cancer, particularly breast cancer. However, in order for a polynucleotide (or a polypeptide) to be useful for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide (or a polypeptide) and a disease or disorder. The presence of a polynucleotide (or a polypeptide) in tissue that is derived from cancer cells (in this case from breast cancer cells) is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polynucleotide (or a polypeptide) to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the

claimed polynucleotide (or a polypeptide) is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide (or a polypeptide) as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

9. Claims 1, 3, 4, 8, 11 and 15 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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11. Claims 1, 3, 4, 8, 11 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 (c) is drawn to an isolated polynucleotide comprising sequences consisting of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 52, claim 1 (d) is drawn to an isolated polynucleotide comprising sequences that hybridize to the sequence provided in SEQ ID NO: 52, claims 1 (e) and (f) are directed to an isolated polynucleotide comprising a sequence having at least 75% [or 90%] sequence identity with the polynucleotide with SEQ ID NO: 52, and claim 1 (g) is drawn to an isolated polynucleotide comprising degenerate variants of the sequence provided in SEQ ID NO: 52. The instant specification only describes the nucleic acid comprising SEQ ID NO: 52. Applicants did not adequately described a representative number of sequences consisting of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 52, or sequences having 75 or 90% sequence identity with SEQ ID NO: 52, or hybridizing to SEQ ID NO: 52 or degenerate variants of SEQ ID NO: 52. In fact, only one sequence was provided, that of SEQ ID NO: 52.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species

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disclosed.” (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID NO: 52 with 379 bp. Thus, applicant has express possession of only one particular sequence, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass all possible 20mers, all possible polynucleotides and oligonucleotides which would hybridize to SEQ ID NO: 52 under moderately stringent conditions (of which there are possibly hundreds of millions), all possible sequences with 75% and 90% sequence identity, and all possible degenerate variants, and only one specific nucleic acid sequence has been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

For example, a polynucleotide comprising a sequence with even 90% sequence identity to SEQ ID NO: 52 would contain 341 bp identical to SEQ ID NO: 52. If the polynucleotide was 379 bp long, it would have 38 bp different from SEQ ID NO: 52. Considering that each of the 38 bp can be one of four bases, the number of sequences of 379 bp 90% identical to SEQ ID NO: 52 would be 4^{38} or about 7.5×10^{22} sequences. Since there is no limit on the length of such polynucleotide, the number of such molecules is in the order of billions.

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It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

“A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. “

In the current situation, the definition of the polynucleotides from claims 1 (c)-(g) lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the one specific sequence, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to “an isolated polynucleotide comprising sequences consisting of at least 20 contiguous residues of the sequence provided in SEQ ID NO: 52”, or “an isolated polynucleotide comprising sequences having at least 90% identity to SEQ ID NO: 52”, for example.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

“...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of “written description” inquiry, whatever is presently claimed.”

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise

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SEQ ID NO: 52. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by a sequence with GenBank accession number AA193540 (May 19, 1997).

GenBank accession No. AA193540 teaches a sequence 37.2% identical to SEQ ID NO: 52, anticipating claim 1 (b)-(d) (see enclosed sequence alignment).

14. Claims 1, 3, 4, 8 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. (WO 01/51638; cited in the IDS).

Regarding claim 1, Yang et al. teach a sequence with SEQ ID NO: 35, which is 100% identical to SEQ ID NO: 52 over bp 314-692 (complement of SEQ ID NO: 52) (page 31 of the sequence listing; page 26, lines 12, 13).

Regarding claim 3, Yang et al. teach vectors comprising the polynucleotide sequences linked to an expression control sequence (page 26, lines 14-23; page 50, lines 20-35).

Regarding claim 4, Yang et al. teach host cells transfected with an expression vector (page 51-54).

Regarding claim 8, Yang et al. teach oligonucleotides which hybridize to SEQ ID NO: 35 (page 40, lines 22-35; page 41, lines 1-30).

Regarding claim 11, Yang et al. teach a composition comprising the polynucleotide and a physiologically acceptable carrier (page 33, lines 29-35; page 34, lines 1, 2; page 60, lines 10-13).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (WO 01/51638; cited in the IDS) and Stratagene Catalog (page 39, 1988).

A) Regarding claim 15, Yang et al. teach oligonucleotides which hybridize to SEQ ID NO: 35 (page 40, lines 22-35; page 41, lines 1-30), but do not teach kits.

B) Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the oligonucleotides of Yang et al. into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic

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reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2)

The other service provided in a kit is quality control" (page 39, column 1).

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1, 3, 4 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 22 and 23 of copending Application No. 10/010,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the 10/010,742 application are species of the instant claims. Specifically, claim 1 of the 10/010,742 application is drawn to an isolated polynucleotide comprising sequence provided in SEQ ID NO: 305 or the complement thereof. Sequence with SEQ ID NO: 305 comprises SEQ ID NO: 52, therefore anticipating claim 1 of the instant application.

Dependent claims 3 and 4 of the instant application are identical to claims 3 and 4 of the 10/010,742 application, and claims 22 and 23 of the 10/010,742 application anticipate claim 11 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka

12/7/06